



U.S. Department of Justice
Civil Division, Federal Programs Branch

MEMO ENDORSED

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February 2, 2021

Hon. Kenneth M. Karas
United States District Court
Southern District of New York
300 Quarropas St.
White Plains, NY 10601-4150

Re: *Regeneron Pharmaceuticals, Inc. v. Alex M. Azar II, et al.*, No. 7:20-cv-10488

Dear Judge Karas,

On November 27, 2020, the Centers for Medicare & Medicaid Services (CMS) published the Most Favored Nation Rule (MFN Interim Final Rule) as an interim final rule in the Federal Register. *See* 85 Fed. Reg. 76,180 (Nov. 27, 2020). Plaintiff Regeneron Pharmaceuticals filed its Complaint on December 11, 2020, raising eight claims challenging the Rule. *See* ECF No. 1. On the same day as Plaintiff filed its Complaint, Plaintiff also moved for a preliminary injunction and temporary restraining order. *See* ECF No. 14.

Following a hearing, this Court issued an order preliminarily enjoining Defendants from implementing the MFN Interim Final Rule as applied to Regeneron's drug EYLEA Injection. *See* ECF No. 45 (Dec. 30, 2020). One other court also enjoined Defendants from implementing the Rule nationwide. *See Cal. Life Sciences Ass'n, et al. v. CMS, et al.*, No. 3:20-cv-08603-VC (N.D. Cal. Dec. 28, 2020), ECF No. 50. A third court entered and extended orders temporarily restraining Defendants from implementing the Rule. *See Ass'n of Community Cancer Centers, et al. v. Azar, et al.*, No. 1:20-cv-03531-CCB, ECF No. 43 (D. Md. Dec. 23, 2020) (entering nationwide temporary restraining order) and ECF No. 53 (extending TRO for additional 14 days).

In light of the courts' orders in the District of Maryland and the Northern District of California, and this Court's order, Defendants did not implement the Rule starting on

January 1, 2021, as originally intended. In addition, the Solicitor General has determined not to appeal the preliminary injunctions issued by this Court or by the Northern District of California.

After the Solicitor General made the determination not to appeal, Defendants were able to reach an agreement to stay proceedings in all cases except this case, and all other cases challenging the MFN Interim Final Rule are presently stayed. *See California Life Sciences Ass'n*, ECF No. 53; *Ass'n of Community Cancer Centers*, ECF No. 59; *Community Oncology Alliance, Inc. v. Azar, et al.*, No. 1:20-cv-3604-EGS, Text Order, Dec. 31, 2020.

Regeneron opposes a stay of this case and instead indicated that it wishes to press forward with summary judgment. As a result of Regeneron's opposition to a stay agreed to in all other lawsuits, Defendants now seek to move this Court for a stay of this case. A stay would give the new administration time to review the Rule and determine whether to issue a final rule after considering comments and to address the procedural concerns identified by the Court's preliminary-injunction order. And a stay would not prejudice Plaintiff, given that this Court (and another) enjoined the challenged agency action and Defendants agreed in other cases that the performance period for any final rule shall not commence earlier than 60 days after the publication of that final rule in the Federal Register. *See, e.g., Ass'n of Community Cancer Centers*, ECF No. 58 at ¶ 7.

A district court retains "broad discretion to stay proceedings as an incident to its power to control its own docket." *Clinton v. Jones*, 520 U.S. 681, 706 (1997). "An agency wishing to reconsider its action should move the court to remand or hold the case in abeyance pending the agency's reconsideration." *Sierra Club v. Van Antwerp*, 560 F. Supp. 2d 21, 23 (D.D.C. 2008). A remand or a stay "serve[s] the interest of allowing [the government] to cure its own potential mistake rather than needlessly wasting the Court's and the parties' resources." *Id.*

The reasons for seeking a stay here are compelling and self-evident. *See FBME Bank Ltd. v. Lew*, 142 F. Supp. 3d 70, 74 (D.D.C. 2015) (granting stay "to allow [agency] to pursue further administrative action to remedy the likely procedural defects that this Court identified in [the agency's] prior rulemaking"). This Court preliminarily enjoined the Rule as to Plaintiff, finding that Plaintiff was "likely to prevail on its claim that the MFN Rule is procedurally invalid" because CMS did not "carr[y] its burden of showing good cause to skip notice and comment procedures." ECF No. 45 at 27. CMS is presently proceeding with the very notice-and-comment rulemaking process sought by Plaintiff. This process may significantly affect or substantially narrow the issues to be considered by this Court or obviate the need for the Court to consider any issues at all, conserving resources that would otherwise have been spent litigating the potential procedural issues

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previously identified by the Court. *See In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 693–94 (S.D.N.Y. 2016) (staying case during the pendency of Agency's rulemaking process). Proceeding with litigation now would be inefficient, needless, and would unnecessarily expend the resources of the parties and the Court.

Nor would Plaintiff be prejudiced by a stay of the litigation. *See Am. Forest Resource Council v. Ashe*, 946 F. Supp. 2d 1, 41 (D.D.C. 2013) (considering whether party opposing remand or stay would be "unduly prejudiced"). The MFN Interim Final Rule was enjoined from going into effect, including specifically as applied to Regeneron's EYELA drug. Those injunctions will remain in place as the agency continues with the rulemaking process. Plaintiff cannot seriously contend that it would be prejudiced by a stay in this litigation to allow for the very notice-and-comment procedures it sought at the outset of this litigation.

As such, Defendants submit this letter requesting a pre-motion conference to address the motion to stay that Defendants seek to file. Defendants propose a stay of the litigation until a final rule based on the MFN Interim Final Rule is published in the Federal Register. In support of this stay, Defendants will further agree that the performance period for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that Rule in the Federal Register. Defendants further agree to file a status report with the Court if Defendants rescind the MFN Interim Final Rule or otherwise determine that they no longer wish to proceed with the MFN Interim Final Rule.

Plaintiff is to respond to this letter by 2/9/21.

So Ordered.



2/2/21

Respectfully submitted,

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CC: All Counsel of record via ECF.